UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5
77 WEST JACKSON BOULEVARD
CHICAGO, IL 60604-3590

DEC 2 2 2011

REPLY TO THE ATTENTION OF:

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Donald Schlafer
Senior Operations Manager
Park Nicollet Health Services
P.O. Box 650
Minneapolis, Minnesota 55440

Dear Mr. Schlafer:

This is to advise you that the U.S. Environmental Protection Agency has determined that Park Nicollet Health Services' facility at 6500 Park Nicollet Blvd., St. Louis Park, Minnesota 55426, (facility) is in violation of 40 C.F.R. Part 63, Subpart WWWWW, the National Emission Standards for Hospital Ethylene Oxide Sterilizers (Subpart WWWWW), promulgated pursuant to Section 112 of the Clean Air Act (CAA or Act). A list of the requirements violated is provided below. We are today issuing to you a Finding of Violation (FOV) for these violations.

Section 112 of the Act, 42 U.S.C. § 7412, requires the establishment of emission standards for hazardous air pollutants (HAPs). Subpart WWWWW was promulgated pursuant to Section 112 of the Act on December 28, 2007. 72 Fed. Reg 73611. Park Nicollet's facility owns and operates an ethylene oxide sterilizer that is subject to the requirements of Subpart WWWWW, including the recordkeeping requirements and the requirement to not sterilize non-full loads except under medically necessary circumstances.

EPA finds that Park Nicollet's facility has violated the above-listed requirements.

Section 113 of the CAA gives us several enforcement options to resolve these violations, including: issuing an administrative compliance order, issuing an administrative penalty order, bringing a judicial civil action and bringing a judicial criminal action.

We are offering you the opportunity to request a conference with us about the violations alleged in the FOV. A conference should be requested within 10 days following receipt of this notice. A conference should be held within 30 days following receipt of this notice. This conference will provide you a chance to present information on the identified violations, any efforts you have taken to comply and the steps you will take to prevent future violations. Please plan for your facility's technical and management personnel to take part in these discussions. You may have an attorney represent and accompany you at this conference.

The EPA contact in this matter is Virginia Palmer. You may call her at (312) 353-2089 if you wish to request a conference. EPA hopes that this FOV will encourage Park Nicollet's compliance with the requirements of the CAA.

Sincerely,

for William L. MacDowell

Cheryl L. Newton
Director
Air and Radiation Division

cc: Jeff T. Connell, Manager
Compliance and Enforcement Section
Industrial Division
Minnesota Pollution Control Agency

Enclosure

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5

IN THE MATTER OF:	)	
	)	
Park Nicollet Health Services	)	**FINDING OF VIOLATION**
Minneapolis, Minnesota	)	
	)	
	)	**EPA-5-12-MN-01**
Proceedings Pursuant to	)	
the Clean Air Act	)	
42 U.S.C.§ § 7401 et seq	)	

NOTICE AND FINDING OF VIOLATION

Park Nicollet Health Services (Park Nicollet) owns and operates a hospital at 6500 Park Nicollet Blvd., St. Louis Park, Minnesota (facility). The facility includes, among other things, an ethylene oxide sterilizer.

The U.S. Environmental Protection Agency is sending this Finding of Violation (FOV) to notify you that we have found violations of the National Emission Standards for Hospital Ethylene Oxide Sterilizers, 40 C.F.R. § 63.10382 *et seq.* Section 113 of the Clean Air Act (CAA), 42 U.S.C. § 7413, provides you with the opportunity to request a conference with us to discuss the violations alleged in the FOV. This conference will provide you a chance to present information on the identified violations, any efforts you have taken to comply, and the steps you will take to prevent future violations. Please plan for the facility's technical and management personnel to take part in these discussions. You may have an attorney represent and accompany you at this conference.

Explanation of Violations

1. Section 112 (a)(1) of the CAA, 42 U.S.C. § 7412(a)(1), defines "major source" as "any stationary source or group of stationary sources located within a contiguous area and under common control that emits or has the potential to emit considering controls, in the aggregate, 10 tons per year or more of any hazardous air pollutant or 25 tons per year or more of any combination of hazardous air pollutants." *See* also 40 C.F.R. § 63.2.

2. Section 112 (a)(2) of the CAA, 42 U.S.C. § 7412(a)(2), defines "area source" as "any stationary source of hazardous air pollutants that is not a major source." *See* also 40 C.F.R. § 63.2.

3. Section 112(b) of the CAA, 42 U.S.C. § 7412(b), as revised in 61 Fed. Reg. 30816 (June 18, 1996), lists 188 Hazardous Air Pollutants (HAPs) that cause adverse health or environmental effects.

4. Section 112(d)(1) of the CAA, 42 U.S.C. § 7412(d)(5), requires the Administrator to promulgate regulations establishing emissions standards for each category or subcategory of major and area sources of HAPs, listed for regulation pursuant to subsection (c) and (e) of Section 112. These standards are known as National Emissions Standards for the Regulation of Hazardous Air Pollutants (NESHAPs).

5. Section 112(d)(2) of the CAA, 42 U.S.C. § 7412(d)(2), of the Act requires that emission standards promulgated under Section 112(d)(1) require "the maximum degree of reduction in emissions of the HAP . . . that the Administrator, taking into consideration the cost of achieving such emission reduction, and any nonair quality health and environmental impacts and energy requirements, determine is achievable for new or existing sources in the category or subcategory to which such emission standard applies." These are known as Maximum Achievable Control Technology (MACT) standards.

6. Section 112(d)(5) of the CAA, 42 U.S.C. § 7412(d)(5), allows the Administrator to elect to promulgate standards or requirements for area sources which provide for the use of generally available control technologies or management practices by such sources to reduce emissions of hazardous air pollutants.

7. Section 112(i)(1) of the CAA, 42 U.S.C. § 7412(i)(1), prohibits the operation of an existing source in violation of the standards, limitations or regulations promulgated under Section 112.

8. Section 114(a)(1) of the CAA, 42 U.S.C. § 7414(a)(1), authorizes the Administrator of EPA to require any person who owns or operates an emission source to make reports and provide information required by the Administrator. The Administrator has delegated this authority to the Regional Administrator of Region 5. The Regional Administrator of Region 5 has delegated this authority to the Director of the Air and Radiation Division.

9. On March 16, 1994, EPA promulgated the General Provisions for the Part 63 NESHAP standards at 40 C.F.R. Part 63, Subpart A, §§ 63.1 - 63.15. 59 Fed. Reg. 12408.

10. 40 C.F.R § 63.1(a)(4)(i) states that "[e]ach relevant standard in this part 63 must identify explicitly whether each provision in this subpart A is or is not included in such relevant standard."

11. 40 C.F.R § 63.4(a)(1) prohibits the owner or operator subject to Part 63 from operating any affected source in violation of the requirements of Part 63.

12. 40 C.F.R § 63.4(a)(2) prohibits the owner or operator subject to Part 63 from failing to keep records, notify, report, or revise reports as required under Part 63.

13. 40 C.F.R § 63.6(c)(1) requires the owner or operator of an existing source to comply with the applicable standard by the compliance date established in the applicable subpart(s) of Part 63.

14. On December 28, 2007, EPA promulgated the National Emission Standards for Hospital Ethylene Oxide Sterilizers at 40 C.F.R. Part 63, Subpart WWWWW, §§ 63.10382 - 63.10448 (Subpart WWWWW). 72 Fed. Reg. 73611.

15. 40 C.F.R § 63.10382 identifies owners or operators of ethylene oxide sterilization facilities at hospitals that are area sources of HAPs as being subject to Subpart WWWWW.

16. 40 C.F.R. § 63.10448 defines "sterilization facility" to mean the group of ethylene oxide sterilization units at a hospital using ethylene oxide gas or an ethylene oxide/inert mixture for the purpose of sterilizing.

17. 40 C.F.R. § 63.10448 defines "sterilization unit" to mean any enclosed vessel that is filled with ethylene oxide gas or an ethylene oxide/inert gas mixture for the purpose of sterilizing. As used in this subpart, the term includes combination sterilization units.

18. 40 C.F.R § 63.10384(a) requires existing sources to comply with the applicable requirements by December 29, 2008.

19. 40 C.F.R § 63.10384(c) requires new sources that started up after December 28, 2007 to comply with the applicable requirements upon startup of the affected source.

20. 40 C.F.R § 63.10390 requires owners or operators of affected sterilization units to sterilize items having a common aeration time at full load, except under medically necessary circumstances. Alternatively, owners or operator may equip their sterilization units with an add-on air pollution control device in accord with 40 C.F.R. § 63.10400.

21. 40 C.F.R. § 63.10448 defines "full load" to mean the maximum number of items that does not impede proper air removal, humidification of the load, or sterilant penetration and evacuation in the sterilization unit.

22. 40 C.F.R. § 63.10448 defines "medically necessary" to mean circumstances that a hospital central services staff, a hospital administrator, or a physician concludes, based on generally accepted medical practices, necessitate sterilizing without a full load in order to protect human health.

23. 40 C.F.R § 63.10400 requires that initial compliance with 40 C.F.R § 63.10390 be demonstrated by the submission of an Initial Notification of Compliance Status.

24. 40 C.F.R § 63.10420 requires that for each sterilization unit not equipped with an air pollution control device, continuous compliance with 40 C.F.R § 63.10390 be demonstrated by "recording the date and time of each sterilization cycle, whether each sterilization cycle contains a full load of items, and, if not, a statement from a hospital central services staff, a hospital administrator, or a physician that it was medically necessary."

25. 40 C.F.R § 63.10430 requires the submission of an Initial Notification of Compliance Status no later than 180 calendar days after the applicable compliance date.

26. 40 C.F.R §§ 63.10432 – 63.10434 require that the records of the Initial Notification of Compliance Status and the records required under 40 C.F.R § 63.104020 be kept for 5 years.

27. Table 1 to Subpart WWWWW shows that 40 C.F.R. §§ 63.4(a)(1), 63.4(a)(2) and 63.6(c)(1) all apply to facilities that are subject to Subpart WWWWW.

28. Park Nicollet owns and operates Methodist Hospital located at 6500 Park Nicollet Blvd., St. Louis Park, Minnesota.

29. Park Nicollet is an owner or operator of an "ethylene oxide sterilization facility" as that term is defined under 40 C.F.R. § 63.10448.

30. On August 29, 2011, Park Nicollet submitted an Initial Notification of Compliance Status pursuant to 40 C.F.R § 63.10430. The Notification stated that an ethylene oxide sterilization unit was installed on October 21, 2009 ("Sterilizer 2"). It also stated that another sterilizer had been in place at the facility before October 21, 2009 ("Sterilizer 1"), which was removed from service prior to installation of Sterilizer 2. Prior to August 29, 2011, Park Nicollet had not submitted an Initial Notification of Compliance Status pursuant to 40 C.F.R. § 63.10430. The Initial Notification of Compliance Status indicated that no add-on air pollution control devices were used by Sterilizer 2.

31. On September 29, 2011, EPA sent an Information Request pursuant to Section 114 of the CAA, 42 U.S.C. § 7414(a)(1) to Park Nicollet (First Information Request), requiring the submission of certain information within 30 days. The Request required, among other things, that Park Nicollet submit specific information about Sterilizer 2, including the following:

    a. ...provide copies of records kept pursuant to 40 C.F.R. § 63.10420 demonstrating the date and time of each sterilization cycle, whether the cycle contained a full load of items, and, if not, a statement from the appropriate personnel that it was medically necessary (Question 3 of First Information Request);
    b. If no records are provided in response to [Question 3 of the First Information Request], provide documentation that demonstrates the number of loads sterilized by the ethylene oxide sterilization unit from October 21, 2009 to the present. Provide documentation identifying how many of those cycles did not contain a full load of items, or, if no documentation is available, provide an estimate and explain the basis for the estimate. Include any relevant documentation to support the estimate. For each cycle that did not contain a full load of items, provide an explanation as to whether it was medically necessary. (Question 4 of the First Information Request).

32. The First Information Request also requested Park Nicollet to provide certain information about Sterilizer 1, including, but not limited to, the date of its installation, its annual ethylene oxide usage, and typical number of sterilization cycles per year.

33. On October 24, 2011, Park Nicollet provided its response to the First Information Request. (October 24, 2011 Response).

34. In the October 24, 2011 Response, Park Nicollet certified that an ethylene oxide sterilizer (Sterilizer 1) was installed at the facility on April 26, 1993 and used approximately 2,200 grams of ethylene oxide annually until its shutdown on October 21, 2009, with a typical number of sterilization cycles per year of 220. Park Nicollet indicated that this sterilizer did not have an add-on air pollution control device.

35. In the October 24, 2011 Response, Park Nicollet provided records for Sterilizer 2 for the period of January 1, 2010 through October 8, 2011. These records provided the dates and times of each sterilization cycle for Sterilizer 2, but the records did not include a determination of whether each sterilization cycle contained a full load, and if the load was not full, there were no recorded statements from an appropriate official under Subpart WWWWW that running such non-full loads was medically necessary. With respect to records for Sterilizer 2 prior to January 1, 2010, the October 24, 2011 Response indicates that "[i]t is necessary to estimate the ETO [ethylene oxide] sterilizer loads processed between October 21, 2009, and December 31, 2009, because these records have been stored off-site with our records storage facility, Iron Mountain." The October 24, 2011 Response further provided an estimate for this time period. The document, titled "RT 2011-10-21 ETO Sterilizer Load Estimate 2009-10-21 to 2009-12-31.docx" indicates an estimate that 28 cycles occurred in this timeframe, and includes a statement that all cycles contained full loads. The document further states: "[e]stimate derived based on consultation with Shauna Morgan, PNHS Operating Room supervisor."

36. On November 9, 2011, EPA notified Park Nicollet via email and letter that its response to the First Information Request was deficient in that the Sterilizer 2 records stored off-site are responsive to the First Information Request and should have been provided. Further, EPA indicated in the November 9, 2011 email and letter that, with respect to the records provided for the period of January 1, 2010 through October 8, 2011, the records do not provide whether each sterilization cycle had contained a full load of items, or if not, a statement from a hospital central services staff, a hospital administrator, or a physician that it was medically necessary, in accord with 40 C.F.R. § 63.10420. EPA indicated that Question 3 of the Information Request requires Park Nicollet to produce copies of such records, and if Park Nicollet did not keep such records, then Park Nicollet must comply with Question 4 for the period of January 1, 2010 through October 8, 2011 and provide documentation identifying how many of the cycles in this time period did not contain a full load of items, or, if no documentation is available, provide an estimate and explain the basis for the estimate, include any relevant documentation to support the estimate. EPA further indicated that Question 4 requires Park Nicollet to provide an explanation as to whether each less-than-full load cycle was medically necessary. With respect to the period prior to January 1, 2010, the November 9, 2011 email and letter indicated that if

Park Nicollet cannot produce records or other documentation concerning sterilization cycle operation for the timeframe of October 21, 2009 to December 31, 2009, it is still required by Question 4 of the Information Request to explain more fully its basis for the estimate it provided in response to the Information Request. The email and letter stated that "[w]e need to understand how Ms. Morgan derived the number cycles that occurred between October 21, 2009 to December 31, 2009, and how she came to the conclusion that all such cycles contained full loads."

37. On November 28, 2011, Park Nicollet submitted its amended response to the September 29, 2011 Section 114 Information Request (September 29, 2011 Response). Park Nicollet indicated that partial loads were run by Sterilizer 2 on 75 days since its compliance date of October 21, 2009. The response further indicates that the number of non-full loads was determined "based on review of records by sterilizer staff and their knowledge of operations." Park Nicollet also indicated that all non-full loads were "necessary based on medical staff requirements." Park Nicollet did not address whether each load was "medically necessary," as that term is defined in 40 C.F.R § 63.10448.

38. On November 15, 2011, EPA sent a Section 114 Information Request to Park Nicollet, requesting, among other things, that Park Nicollet submit records of the loads run by Sterilizer 1 and identify whether each load was a full or partial load and whether each was medically necessary (Second Information Request).

39. On December 14, 2011, Park Nicollet provided its response to the Second Information Request. Park Nicollet provided records of the date and time of sterilization cycles for Sterilizer 1 for the period of February 1, 2009 and October 21, 2009. However such records did not identify for each sterilization cycle whether it was run at full load and did not have any recorded statements from appropriate officials under Subpart WWWWW that non-full loads were medically necessary. Park Nicollet did not have records for Sterilizer 1 for the period of December 29, 2008 to January 31, 2009. Park Nicollet provided a document indicating that it estimates that partial loads were run by Sterilizer 1 on 10 days between December 29, 2008 and October 21, 2009. The document further indicated that its estimate of non-full loads was determined "based on review of records by sterilizer staff and their knowledge of operations" and that all non-full loads were "necessary based on medical staff requirements." Park Nicollet did not address whether each load was "medically necessary," as that term is defined in 40 C.F.R § 63.10448.

40. Sterilizer 1 was an existing source under Subpart WWWWW. Thus, pursuant to 40 C.F.R § 63.10384(a), initial compliance with Subpart WWWWW was required by December 29, 2008.

41. Pursuant to 40 C.F.R § 63.10430, the Initial Notification for Sterilizer 1 was due by June 27, 2009 (180 calendar days after December 29, 2008).

42. Sterilizer 2 is a new source under Subpart WWWWW. Thus, pursuant to 40 C.F.R § 63.10384(c), initial compliance was required by October 21, 2009, its startup date.

43. Pursuant to 40 C.F.R § 63.10430, the Initial Notification for Sterilizer 2 was due by April 20, 2010 (180 calendar days after October 21, 2009).

44. As described in Paragraphs 25 - 31, Park Nicollet failed to submit the Initial Notification of Compliance status for Sterilizer 1 within 180 days of the applicable compliance date, in violation of 40 C.F.R §§ 63.4(a)(1), 63.4(a)(2), 63.10430 and Section 112(i)(1) of the CAA.

45. As described in Paragraphs 25 - 31, Park Nicollet failed to submit the Initial Notification of Compliance status for Sterilizer 2 within 180 days of the applicable compliance date, in violation of 40 C.F.R §§ 63.4(a)(1), 63.4(a)(2), 63.10430 and Section 112(i)(1) of the CAA.

46. As described in Paragraphs 25 - 31, Park Nicollet failed to demonstrate continuous compliance for Sterilizers 1 and 2 by failing to keep records of whether each sterilization cycle contained a full load of items and, if not, a statement from an appropriate person that it was medically necessary, in violation of 40 C.F.R §§ 63.4(a)(1), 63.4(a)(2), 63.10420 and Section 112(i)(1) of the CAA. Park Nicollet additionally failed to keep any records of Sterilizer 1 operation during the period of December 29, 2008 and January 31, 2009, in violation of 40 C.F.R. §§ 63.4(a)(1), 63.4(a)(2), 63.10420, and Section 112(i)(1) of the CAA.

47. Based on its responses to EPA's Information Requests, Park Nicollet failed to comply with the Subpart WWWWW work practice standards under 40 C.F.R § 63.10390, as it did not assure that its ethylene oxide sterilizers were run with items with a common aeration time only at full load except under medically necessary circumstances, in violation of 40 C.F.R §§ 63.4(a)(1), 63.10390, and Section 112(i)(1) of the CAA.

12/22/11
Date

Cheryl L. Newton
Director
Air and Radiation Division

CERTIFICATE OF MAILING

I, Loretta Shaffer, certify that I sent a Notice and Finding of Violation, No. EPA-5-12-MN-01, by Certified Mail, Return Receipt Requested, to:

Donald Schlafer, Senior Operations Manager
Engineering & Maintenance
Park Nicollet Health Services
P.O. Box 650
Minneapolis, Minnesota 55440

I also certify that I sent copies of the Notice of Violation and Finding of Violation by first-class mail to:

Jeff T. Connell, Manager
Compliance and Enforcement Section
Industrial Division
Minnesota Pollution Control Agency
520 Lafayette Road
St. Paul, Minnesota 55155-4194

On the 27 day of December 2011.

Loretta Shaffer

Loretta Shaffer
Administrative Professional Assistant
Planning and Administration Section

CERTIFIED MAIL RECEIPT NUMBER: 7009 1680 0000 7673 9030